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SEP 9 4 2003

**To:** Examiner Christopher Yaen  
 Art Group 1642

**From:** Leonard R. Svensson/Susan W. Gorman

**Fax:** 703-308-4242

**Pages:** 25 (including cover sheet)

**Phone:** 703-305-3586

**Date:** September 17, 2003

**Your Ref.:** 09/889,300

**Our Ref.:** 0147-0229P

**Re:** Materials for Interview on 09/19/2003

**CC:**

**Urgent**  **For Review**  **Please Comment**  **Please Reply**  **Please Recycle**

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**Comments:**

Dear Examiner Yaen,

Please find attached the following materials for the interview on Friday, September 19 at 3:30 p.m.:

- UNOFFICIAL Outline of Interview**
- UNOFFICIAL Proposed Amended Claims**
- UNOFFICIAL Declaration of Hans Loibner dated September 9, 2003**
- UNOFFICIAL Declaration of Hans Loibner dated July 17, 2002. (see 2<sup>nd</sup> facsimile)**

Best regards,

Leonard R. Svensson  
 Susan W. Gorman

**Outline of Interview****1. Enablement Rejections**

**1.1** Claims 1 and 6: no evidence that one skilled in the art could make additional antibodies against EpCAM that would work in the invention.

- Loibner Declaration #1: use of two different antibody preparations (HE-2 and 73-3; HE-2 and KS1/4)
- Loibner Declaration #2: results of clinical trials using a non-HE-2, anti-EpCam antibody, specifically antibody 17-A1.

**1.2** Claims 1-9: use of the terms "vaccination" and "prevention".

- Amendment to claims deleting "vaccination" and "prevention."

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**2. Novelty Rejections**

**2.1** Claims 1-3 (Braun et al.)

- Enclosed certified translation of priority document

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**3. Obviousness Rejections**

**3.1** Claim 7 (Braun in view of Pardoll):

- Presentation of certified translation of priority document

**DRAFT**

## Proposed Amended Claims

1. ~~(Twice-Currently Amended) An individual dosage form of a pharmaceutical composition for human vaccination to actively immunize cancer patients for the prevention of the development of metastasis and treatment of cancer disease comprising a dose of 0.01-4 mg of at least one first antibody directed against the cellular membrane antigen EpCAM.~~
2. ~~(Currently Amended) The pharmaceutical composition individual dosage form of claim 1, wherein said antibody is of animal origin.~~
3. ~~(Currently Amended) The pharmaceutical composition individual dosage form of claim 1, wherein said antibody is a monoclonal antibody.~~
4. ~~(Currently Amended) The pharmaceutical composition individual dosage form of claim 3, wherein said first antibody is a murine monoclonal antibody, wherein the variable region of the heavy chain is the amino acid sequence as shown in SEQ ID NO:1 and wherein the variable region of the light chain is the amino acid sequence as shown in SEQ ID NO:2.~~
5. ~~(Currently Twice-Amended) The pharmaceutical composition individual dosage form of any one of claims 1-3, wherein said first antibody has the same specificity of binding as that antibody defined in claim 4.~~
6. ~~(Currently Twice-Amended) The pharmaceutical composition individual dosage form of claim 1, wherein two or more antibodies, which are further comprising at least a second antibody directed against different membrane antigens or against a different epitope/epitope of said EpCam membrane antigen, are used in combination with each other.~~
7. ~~(Currently Amended) The pharmaceutical composition individual dosage form of claim 1, further comprising at least one vaccine adjuvant.~~

**DRAFT**

8. (Currently Amended) A method of ~~vaccination against cancer therapy~~ comprising administering to a human patient in need thereof the ~~pharmaceutical composition of claim 1 at a dosage in the range of 0.01 to 4 mg per dose of a first antibody directed against the cellular membrane antigen EpCAM.~~
9. (Currently Amended) The method according to claim 8, wherein said ~~pharmaceutical composition dose~~ is administered by subcutaneous, intradermal or intramuscular injection.
10. (Currently Amended New) The method according to claim 8, wherein said first antibody is a pharmaceutical composition for therapeutic vaccination against cancer comprising at least one monoclonal antibody of animal origin directed against the cellular membrane antigen Ep-CAM, wherein one of said at least one first antibody has the amino acid sequence of SEQ ID NO:1 for the variable region of the heavy chain and the amino acid sequence of SEQ ID NO:2 for the variable region of the light chain.
11. (Currently Amended New) The pharmaceutical composition method of claim 10, which further comprisesing at least one vaccine adjuvant.
12. (Currently Amended New) A-The method of claim 8 or 10, wherein said dose is 0.5 mg therapeutic vaccination against cancer comprising administering to a patient in need thereof the pharmaceutical composition of claim 10 at a dosage in the range of 0.01 to 4 mg antibody.

**DRAFT**

13. (NewPreviously Presented) The method according to claim 12, wherein said pharmaceutical composition dose is administered by subcutaneous, intradermal or intramuscular injection.

14. (Currently AmendedNew) An individual dosage form of a pharmaceutical composition for humans method of vaccination against cancer comprising administering to a patient in need thereof the pharmaceutical composition of claim 1 at a dosage in the range of 0.01 to 4 mg of a first monoclonal antibody of animal origin directed against the cellular membrane antigen EpCAM, wherein said first antibody has the amino acid sequence of SEQ ID NO.:1 for the variable region of the heavy chain and the amino acid sequence of SEQ ID NO.:2 for the variable region of the light chain for the prevention of the development of metastasis and treatment of cancer disease.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: Yaen; Christopher H  
Group Art Unit: 1642

Applicants: Eckert, Helmut et al.

Serial No.: 09/889,300

Filed: September 13, 2001

For: USE OF ANTIBODIES FOR THE VACCINATION AGAINST CANCER

Hon. Assistant Commissioner  
For Patents  
Washington, D.C. 20231

## DECLARATION UNDER 37 C.F.R. § 1.132 of HANS LOIBNER

I, Hans Loibner, hereby declare and state as follows:

1. I am one of the co-inventors of the subject matter of the above-identified application.
2. I am currently Chief Executive Officer of Igeneon Krebs-Immuntherapie-Forschungs- und Entwicklungs-AG, a research based biotechnology company. Prior to that I was working as head of R&D of cancer vaccines for more than 15 years. My Curriculum Vitae is enclosed as Exhibit 1.
3. I have published over 15 scientific papers in the field of cancer research, a list of publications is enclosed as Exhibit 2.
4. I make this declaration to make record of supplemental results, which further demonstrate the safety and efficacy of a vaccine described in the above-identified application. Specifically I make this declaration to present the following clinical data derived from phase I and phase II clinical trials generated under my direction and supervision.
5. I declare that following description of clinical results includes safety, tolerability and efficacy of an anti-EpCAM antibody vaccine in treating cancer patients, wherein the patients are actively immunized by the anti-EpCAM antibody vaccine and the production of autologous antibodies can be actively induced thereby.

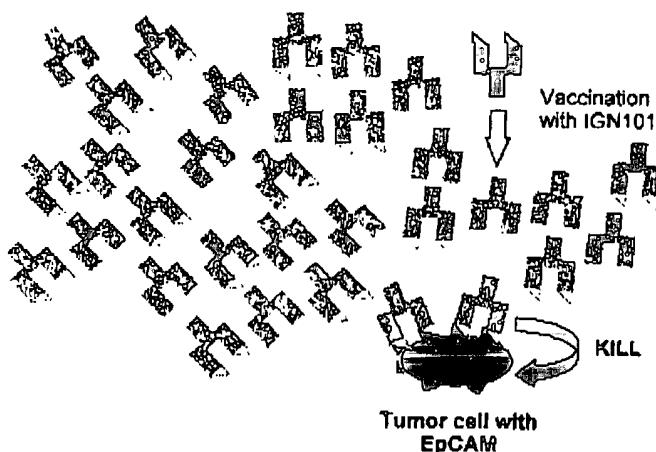
6. Mode of Action of the Vaccine:

IGN101 consists of a xenogeneic (foreign) protein used as vaccine antigen in an immunogenic formulation. This xenogeneic vaccine antigen is the murine monoclonal antibody 17-1A.

IGN101 has structural epitopes (mimotopes) related to EpCAM and elicits an immune response that is directed towards the vaccine antigen and because of its structural similarity, towards EpCAM.

Antibodies induced by vaccination with IGN101 recognize epithelial cancer cells as "foreign" and activate effector functions such as complement-dependent cytotoxicity (CDC) and antibody dependent cellular cytotoxicity (ADCC). These effector mechanisms may be directed to eliminate single carcinoma cells disseminated from the primary tumor.

### Mechanism of action of IGN101



#### 7. Summary of Clinical Trial Studies:

A Phase I clinical trial with IGN101 was completed at the Medical University Clinic Graz, Austria in 2001. 18 patients with biopsy proven carcinoma that failed conventional therapy or were deemed refractory to standard agents, were enrolled. Patients received 0.5 mg IGN101 subcutaneously on days 1, 15, 29 and 57.

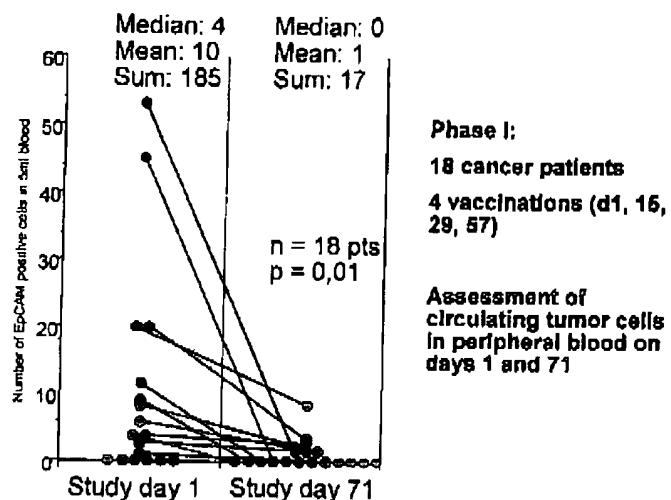
Immunological assessments included the total humoral immune response, the IgG/IgM level and the amount of EpCAM specific antibodies. Evidence of anti-tumor effects were assessed by determination of the number of EpCAM positive tumor cells in blood measured on days 1, 29 and 71.

#### Phase I Results

- **Excellent tolerability:** The only side effects seen were mild to moderate transient erythema (reddening of the skin) at the injection site, no systemic side effects were observed.
- **High overall and specific immunogenicity:** Seroconversion occurred in all patients and a secondary IgG antibody response was induced, indicating T-cell help and memory. In all patients anti-EpCAM IgG was induced. In 10/18 patients anti-EpCAM IgG 5-31 µg/ml serum was isolated.
- **No influence of prior chemotherapy (CT) on immunogenicity:** 12/18 patients received CT at least six weeks prior to vaccinations. These patients showed a similar overall and specific immune response compared to those without CT.

- **Early indication of efficacy:** The number of circulating EpCAM+ cells in blood significantly decreased during the vaccination course. Furthermore, in some patients a decrease or stabilization of tumor markers was seen. 15/18 patients showed stable disease for at least 2 months.

**Figure 1: Reduction of EpCAM positive cells**



A Phase II clinical trial was completed in 2002 at the Medical University Clinic Graz, Austria. Objective of the study was to assess the influence of concomitant chemotherapy (CT) on immunogenicity of IGN101 in patients with carcinoma likely to express EpCAM. Three different, frequently used CT regimens were analyzed. Results showed specific immunogenicity in almost all patients, comparable to results of Phase I, despite concomitant chemotherapy and no significant negative impact of the concomitant chemotherapy. The results allow further clinical testing of IGN101 in a wide range of clinical settings, including major cancer indications and stages where chemotherapy is standard of care.

Two Phase II studies and a Phase II/III study are currently under way. In an open-label Phase II study, IGN101 is being tested in 45 patients with epithelial cancers. Primary objective is assessment of surrogate efficacy of IGN101 against circulating tumor cells in blood. The study started in 2002 at the Medical University Clinic Graz, the University Clinic Innsbruck, the General Hospital (AKH) Vienna, Austria and the Charité, Berlin, Germany

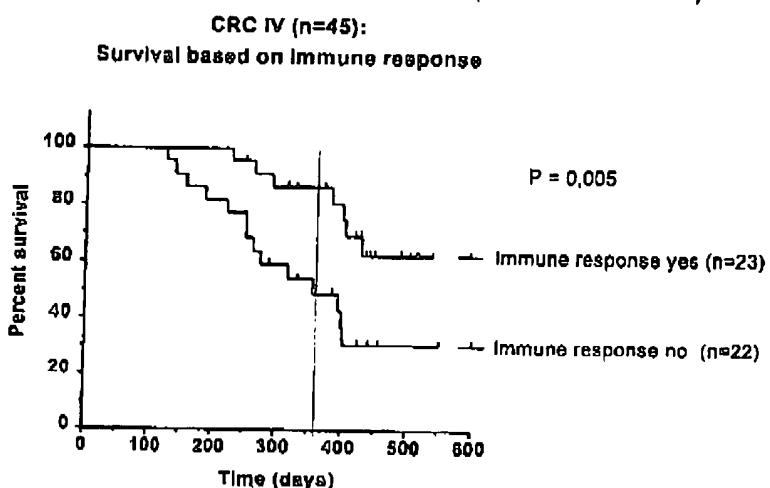
### Phase II efficacy trial

A placebo-controlled, double blind Phase II trial with IGN101 in 220 patients with three epithelial cancers (lung, colorectal, esophageal/gastric cancer) stage III and IV is currently being conducted. The study started in September 2001. Patient recruitment has ended beginning of July 2003. The study is performed under GCP rules and is expected to end in Q4 2003. The clinical end point is overall survival.

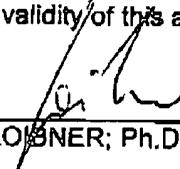
A blinded analysis of immune responses was performed with sera of 91 colorectal patients (45 in stage IV and 46 in stage III). 50.4% of these patients proved an immune response (50% is the theoretical number based on 1:1 randomization of placebo- and verum-treated patients).

### Phase II Results

- **No influence of concomitant CT on immunogenicity:** In an open-label Phase II study, IGN101 was tested in 47 patients in direct combination with different chemotherapies to evaluate the influence of cytotoxic therapies on immunogenicity. Chemotherapy cycles started at the day of first vaccination and were continued as usual. Chemotherapies were grouped into taxane/anthracyclines, platinum compounds and others. As result, all patients mounted an immune response. A comparison of the immune responses with those observed in Phase I showed that overall and EpCAM-specific immunogenicity was mostly retained despite of different immunosuppressive CT.
- **Promising first survival benefit results:** In the context of the ongoing double blind placebo-controlled Phase II trial, a blinded analysis of immune responses was performed with sera of 91 colorectal patients (45 in stage IV and 46 in stage III). 50.4% of these patients proved an immune response to the vaccine antigen in IGN101 (50% is the theoretical number based on the 1:1 randomization of placebo- and IGN101-treated patients). The immune response results of the CRC stage IV patients were correlated with survival: The 1-year survival rate of the CRC IV patients without immune response (n=22) is 45%, corresponding well to the results of a large related database (Cochrane Library 2003, issue 1; 1-year survival 44.3%). The 1-year survival rate of the CRC IV patients with a proven immune response to IGN101 (n=23) amounts to 85%. This difference is statistically significant ( $p=0.005$ ). The corresponding Kaplan-Meier survival curves are shown in figure 2. Patients in both groups are well balanced with regard to Karnofski performance status, liver enzyme values and treatment by concomitant chemotherapy.

**Figure 2: Survival in Metastatic CRC (colorectal cancer)**

8. I further declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the validity of this application or any patent issuing thereon.



HANS LOJBNER; Ph.D.

Signed this 9 day of  
September, 2003  
At Vienna, Austria

**Hans Loibner**  
**Address:** igeneon Krebs-Immuntherapie Forschungs- und Entwicklungs-AG  
 Brunner Strasse 69/3, 1230 Vienna/Austria  
**Phone:** +43/1/90250 111 **Fax:** +43/1/90250 901  
[hans.loibner@igeneon.com](mailto:hans.loibner@igeneon.com)

#### PROFESSIONAL EXPERIENCE

igeneon, Vienna, Austria as of 1999  
igeneon Krebs-Immuntherapie Forschungs- und Entwicklungs-AG

Novartis (Sandoz) Forschungsinstitut, Vienna, Austria

**Head of Oncology Group Vienna**

- Support of the anti-idiotypic antibody vaccine MMA 383
- Basic research in the area of active specific immunotherapy

1997 - 1999

**Head of MMA 383 Support Group**

- Support of further development of the anti-idiotypic antibody vaccine MMA 383, aiming at initiation of clinical proof of concept trials 1/1997

1996 - 1997

**Head of Department "Genetics"**

- Establishment of highly automatized methods for comprehensive analysis of expressed genes as novel tool for identification of molecular targets for disease intervention in all disease areas of interest for Sandoz Pharma
- Shaping of the collaboration with Prof. Lehrach, MPI Berlin regarding fingerprinting analysis of expressed genes
- Responsibility for preclinical development of an anti-idiotypic antibody vaccine against epithelial cancer (MMA 383) generated at SFI in the context of an international project team

1995 - 1996

**Head of Department "Special Projects"**

- Assessment of immunological and serological parameters of cancer patients in the context of clinical studies with cancer immunotherapy approaches developed at SFI
- Generation and preclinical profiling of new projects in specific cancer immunotherapy

1990 - 1994

**Head of international project teams**

- Responsibility for coordinated international preclinical and in particular clinical development of projects in specific cancer immunotherapy (ABL 364: monoclonal antibody for passive immunotherapy, SCV 106: anti-idiotypic antibody vaccine for therapeutic vaccination), together with internal departments and involved external clinical centers.

1987 - 1994

**Head of Department "Antibodies"**

- Discovery, profiling and development of antibody-based immunotherapies against cancer, in particular tumor specific monoclonal antibodies for passive immunotherapy and anti-idiotypic antibodies for therapeutic vaccination
- Generation and characterization of new monoclonal antibodies for all research purposes of the institute
- Fermentation of bacteria as well as of mammalian cells for production of proteins
- Protein purification and -analytics; automated peptide synthesis

1986 - 1989

**Head of Department "Molecular Enzymology", Head of working group**

**"Aminoglycoside-Antibiotics"**, Head of a chemistry laboratory, postdoctoral fellow at Sandoz Forschungsinstitut (SFI)

1977-1986

#### EDUCATION

**Ph. D.**

1977

**Thesis at Department of Organic Chemistry**

Professor Dr. E. Zbiral, University Vienna, synthetic organic chemistry

1975 - 1977

**List of publications  
Hans Loibner, Ph.D.**

**Full papers and book chapters**

**Increased expression of the blood group related LeY antigen on synovial fluid granulocytes of patients with inflammatory joint diseases**  
M. Dettke, G. Palfi, E. Pursch, E. Leeb, J. Smolen and H. Loibner  
*Rheumatology (Oxford)*. 2001 Sep;40(9):1033-7.

**Activation-dependent expression of the blood group related Lewis Y antigen on peripheral blood neutrophils**  
M. Dettke, G. Palfi and H. Loibner  
*J Leukoc Biol.* 2000 Oct;68(4):511-4.

**Different types of FCgamma-receptors are involved in anti-Lewis Y antibody induced effector functions in vitro.**  
M. Dettke, H. Loibner.  
*Br J Cancer* 82, 441-445 (2000)

**A double blind randomized trial comparing immunization with anti-idiotype goat antibody vaccine SCV 106 versus unspecific goat antibodies in patients with metastatic colorectal cancer**  
H. Samonigg, M. Wilders-Truschnig, I. Kuss, R. Plot, H. Stöger, M. Schmid, T. Bauernhofer, A. Tiran, T. Pieber, L. Havelec and H. Loibner  
*J. Immunother* 22, 481-488 (1999)

**Humanized Anti-Lewis Y Antibodies: In Vitro Properties and Pharmacokinetics in Rhesus Monkeys**  
M. S. Co, J. Baker, K. Bednarik, E. Janzek, W. Neruda, P. Mayer, R. Plot, B. Stumper, M. Casquez, Cary Queen and H. Loibner  
*Cancer Research* 56, 1118-1125 (1996)

**Reduction of metastatic carcinoma cells in bone marrow by intravenously administered monoclonal antibody: Towards a novel surrogate marker for monitoring adjuvant therapies of solid tumors**  
G. Schlimok, K. Pantel, H. Loibner, I. Fackler-Schwalbe, G. Riethmüller  
*Eur. J. Cancer* 31A, 1799-1803 (1995)

**Enzymatic synthesis of analogs of bacterial lipid A and design of biologically active LPS-antagonists and -mimetics.**  
M. Bulusu, H. Hildebrandt, C. Lam, E. Liehl, H. Loibner, I. Macher, D. Scholz, E. Schütze, P. Stütz, H. Vyplel, F. Unger  
*Pure and Applied Chemistry* 66, 2171-2174 (1994);

**Enhancement of retroviral infection in vitro by anti-LeY IgG: Reversal by humanization of monoclonal mouse antibody**  
J. E. Hansen, A. M. Sorensen, M. Arendrup, C. Nielsen, S. Oloffson, J. O. Nielsen, E. Janzek, H. Loibner  
*APMIS* 101, 711-718 (1993)

Model for measurement of micrometastasis in epithelial tumours  
G.Schlomok, K.Pantel, F.Lindemann, H.Loibner, G.Riethmüller  
In: Hemopoietic Growth Factors and Mononuclear Phagocytes; Van Furth R. (ed.), pp 168-176 (1993)

Immune response to tumor antigens in a patient with colorectal cancer after immunization with anti-idiotype antibody  
H.Samonigg, M.Wilders-Truschnig, H.Loibner, R.Plot, A.Rot, I.Kuss, G.Werner, H.Stöger, M.Wrann, D.Herlyn, H.Koprowski  
Clin. Immunol. and Immunopath. 65, 271-277 (1992)

Enzymatic synthesis and comparative biological evaluation of a phosphonate analog of the lipid A precursor  
D.Scholz, K.Bednarik, G.Ehn, W.Neruda, E.Janzek, H.Loibner, K.Briner and A.Vasella  
J. Med. Chemistry 35, 2070-2074 (1992)

Phase I/II study of monoclonal antibody against Lewis Y hapten in relapsed small cell lung cancer  
R.A.Stahel, H.Lacroix, J.P.Sculier, R.Morant, J.Richner, E.Janzek, H.Loibner and H.Blythman  
Ann. of Oncology 3, 319-320 (1992)

Synthesis of fluorinated analogues of Lipid A  
H.Vyptiel, D.Scholz, H.Loibner, M.Kern, K.Bednarik and H.Schaller  
Tetrahedron Letters 33, 1261-1264 (1992)

Polyclonal anti-idiotypic antibodies mimicking the small cell lung carcinoma antigen cluster-5A interact with a panel of antibodies and induce specific immune response in animals  
C.Zwicky, R.A.Stahel, H.Jaksche, R.Waibel, H.P.Lehmann and H.Loibner  
Brit. J. Cancer 63, Suppl. XIV, 67-70 (1991)

Biological activity in the human system of isotype variants of oligosaccharide Y specific murine Mabs  
D.Scholz, M.Lubeck, H.Loibner, J.McDonald-Smith, Y.Kimoto, H.Koprowski and Z.Steplewski  
Cancer Immunol. Immunther. 33, 153-157 (1991)

Tumor cell lysis and tumor growth inhibition by the isotype variants of Mab BR55-2 directed against Y oligosaccharide  
Z.Steplewski, M.Lubeck, D.Scholz, H.Loibner, J.McDonald Smith and H.Koprowski  
In Vivo 5, 79-84 (1991)

Treatment of a colon carcinoma patient with SDZ SCV 106 (anti-id 17-1A), a case study  
H.Samonigg, H.Loibner, M.Wilders-Truschnig, R.Plot, H.P.Brezsinschek, A.Rot, I.Kuss, G.Werner, H.Stöger, M.Wrann, M.Schmid, G.H.Schneider, K.Arian-Schad, M.Klimpfinger, D.Herlyn and H.Koprowski  
Proceedings of an International Symposium organized by the Department of Internal Medicine, Bamherzige Brüder Eggenberg Hospital, Graz, March 16, 1990; 1991 in: Modern aspects of tumor diagnosis and treatment. O.Eber, P.Lind, W.Langsteiger (Eds.)

Immunoreactivity of patient with colorectal cancer in metastasis after immunization with antiidiotypes

H.Loibner, R.Plot, A.Rot, G.Werner, M.Wrann, H.Samonigg, M.Schmid, H.Stöger, M.Truschnigg, D.Herlyn et al.  
*Lancet* 335, 171 (1990)

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Z.Steplewski, M.Błaszczyk-Thurin, M.Lubeck, H.Loibner, D.Scholz, H.Koprowski  
*Hybridoma* 9, 201-210 (1990)

Chemical synthesis of endotoxin analogs and some structure activity relationships  
P.L.Stütz, H.Aschauer, J.Hildebrandt, C.Lam, H.Loibner, I.Macher, D.Scholz, E.Schütze, H.Vyplej

Int. Congr.Ser.- Excerpta Med. 923, in: Cell. Mol. Aspects Endotoxin React. p129-144, Eds.: Nowotny A., Spitzer J., Ziegler E., Amsterdam, Elsevier (1990)

Selective one step synthesis of N-acetylated polyamines and a HPLC-system for their analytical separation

H.Loibner, G.Seidl

Recent Progress in Polyamine Research, 1985; L.Selmeci, M.E.Brosnan, N.Seiler (Eds.), p597-605 (1985)

*Reductive methylation of primary and secondary amines with formaldehyde and phosphorous acid salts*

H.Loibner, A.Pruckner, A.Stütz  
*Tetrahedron Lett.* 25, 2535-2536 (1984)

*Synthesis and structure/activity relationships of new guanidino derivatives of aminoglycoside antibiotics*

W.Streicher, H.Loibner, J.Hildebrandt, F.Turnowsky  
*Drugs Exp. Clin. Res.* 9, 591-598 (1983)

Role of the 1-amino group in aminocyclitol antibiotics: Synthesis of 1-deaminogentamicin C2

M.Philippe, B.Quiclet-Sire, A.M.Sepulchre, S.D.Gero, H.Loibner, W.Streicher, P.Stütz, N.Moreau

*J. Antibiot.* 36, 250-255 (1983)

1-N-Acylation of gentamicin C1a by a cyclic, chiral gamma-amino-alpha-hydroxy acid related to the (S)-4-amino-2-hydroxybutyric acid

M.Philippe, A.M.Sepulchre, S.D.Gero, H.Loibner, W.Streicher, P.Stütz  
*J. Antibiot.* 35, 1507-1512 (1982)

A low-cost medium-pressure liquid chromatography system for preparative separations

H.Loibner, G.Seidl

*Chromatographia* 12, 600-604 (1979)

Synthesis of 3-deoxy-3-aminovitamin D3 and 3-deoxy-3-epiamino-vitamin D3 and D2

H.Loibner, E.Zbiral

*Tetrahedron Lett.* 34, 713-716 (1978)

Reactions with organophosphorus compounds, XLIII. Structural modifications of nucleosides by means of triphenylphosphane/diethyl azodicarboxylate

H. Loibner, E. Zbiral

Justus Liebigs Ann. Chem. 1, 78-86 (1978)

Reactions using triphenylphosphane/azodicarboxylate. 2. Reactions with organophosphorus compounds. XLII. Nucleophilic substitution reactions of hydroxysteroids using triphenylphosphane/diethylazodicarboxylate

H. Loibner, E. Zbiral; Helv. Chim. Acta 60, 417-425 (1977)

Reactions with organophosphorus compounds. XLI. New synthetic aspects of the triphenylphosphine-diethyl azodicarboxylate-hydroxy compound system

H. Loibner, E. Zbiral

Helv. Chim. Acta 59, 2100-2113 (1976)

**Poster and oral presentations (1990-2003)**

Humanized monoclonal antibody IGN311 targeting Lewis Y: Pharmakokinetics and toxicology in Rhesus monkeys

Norbert Eller, Otto Dobhoff, Erich Wasserbauer, Evelyne Janzek, Gottfried Himmier and Hans Loibner

Tumor Markers: Discovery to Practice, Santa Barbara 2003

Comparison of three different methods for the quantification of circulating tumor cells in blood of patients with epithelial cancers

Andreas Obwaller, Hans Loibner, Gottfried Himmier, Bernhard Peball, Susanne Grunt, Philipp Oberkleiner, Thomas Bauernhofer, Hellmut Samonigg;

Tumor Cell Dissemination in Breast Cancer 2003, Tübingen

Vaccination with alum-adsorbed antibodies against EpCAM directly induces anti-EpCAM antibodies

Gottfried Himmier, Evelyne Janzek, Hans Loibner, Manfred Schuster, Günter Waxenecker, Hellmut Samonigg;

Tumor Cell Dissemination in Breast Cancer 2003, Tübingen

Treatment of breast cancer patients with the cancer vaccine IGN101 that induces an immune response against the pan-carcinoma glycoprotein EpCAM

Hellmut Samonigg, Hans Loibner, Marija Balic, Guenter Hofmann, Manfred Schuster and Gottfried Himmier;

Tumor Cell Dissemination in Breast Cancer 2003, Tübingen

Evaluation of epithelial cell enumeration methods to detect tumor cells in blood of carcinoma patients

Andreas Obwaller, Hans Loibner, Gottfried Himmier, Bernhard Peball, Susanne Grunt, Philipp Oberkleiner, Günter Waxenecker, Alexander Van Der Kooi, Gerald V. Doyle, Leon WMM Terstappen, Thomas Bauernhofer, Hellmut Samonigg;

Tumor Markers: Discovery to Practice, Santa Barbara 2003

Vaccination with alum-adsorbed antibodies against EpCAM directly induces anti-EpCAM antibodies

Gottfried Himmier, Evelyne Janzek, Hans Loibner, Manfred Schuster, Günter Waxenecker, Hellmut Samonigg;

Development Of Therapeutic Cancer Vaccines, Los Angeles 2003, 27.4. - 29.4.2003

Evaluation of epithelial cell enumeration methods to detect tumor cells in blood of carcinoma patients

Andreas Obwaller, Hans Loibner, Gottfried Himmier, Bernhard Peball, Susanne Grunt, Philipp Oberkleiner, Günter Waxenecker, Alexander Van Der Kooi, Gerald V. Doyle, Leon WMM Terstappen, Thomas Bauernhofer, Hellmut Samonigg;

Development Of Therapeutic Cancer Vaccines, Los Angeles 2003, 27.4. - 29.4.2003

Murine monoclonal antibody 17-1A used as vaccine antigen (IGN101): Direct induction of anti-EpCAM antibodies by vaccination of cancer patients

Manfred Schuster, Hans Loibner, Evelyne Janzek, Gottfried Himmier, Jungbauer Alois, Rainer Hahn, Astrid Dürauer, Hellmut Samonigg;

ASCO 2003, Chicago, 39th Meeting of the American Association of Clinical Oncology, 31.5 - 3.6.2003

List of publication  
Hans Loibner, Ph.D.  
September 2003

Phase II trial to explore the influence of concomitant chemotherapy on the immunogenicity of the cancer vaccine IGN101 in patients with epithelial cancers.

H.Samonigg , G.Hofmann , T.Bauernhofer , M.Balic , H.Stoeger , G.Himmler, M.Schuster, F.Rosenkaimer, F.Groiss, H.Loibner;

ASCO 2003, Chicago, 39th Meeting of the American Association of Clinical Oncology, 31.5 - 3.6.2003

Reduction of EpCAM positive cells in peripheral blood of patients with epithelial cancers following vaccination with the cancer vaccine

Gottfried Himmler, Guenter Waxenecker, Thomas Putz, Bernhard Peball, Susanne Grunt, Guenter Hofmann, Sabine Schagerl, Hellmut Samonigg, Hans Loibner; Eurocancer 2003, Paris, 8.7. - 10.7.2003

Comparison of EpCAM expression in different tumor types and normal tissues - impact on prognosis

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**Inventorship or co-inventorship (US patents, EP patents and WO publications)****US5562903****HUMANIZED ANTIBODIES THAT RECOGNIZE DIFUCOSYL LEWIS BLOOD GROUP ANTIGENS Y-6 AND B-7-2****US5523085****MONOCLONAL ANTIBODY IN DESTRUCTION OF SMALL CELL LUNG CARCINOMA****US4503046****1-NITRO-AMINOGLYCOSIDE DERIVATIVES, PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND SUCH DERIVATIVES FOR USE AS PHARMACEUTICALS****EP1140168****VACCINATION AGAINST CANCER****EP 1 230 932****USE OF ANTIBODIES FOR ANTICANCER VACCINATION****EP0644947****ANTI-IDIOTYPIC MONOCLONAL ANTIBODIES AGAINST THE LEWIS Y-SPECIFIC MONOCLONAL ANTIBODY BR55-2 AND THEIR USES.****EP0547079****NEW USE OF A MONOCLONAL ANTIBODY.****EP0528767****ANTIBODY DERIVATIVES.****EP0445078****NEW USE OF A MONOCLONAL ANTIBODY.****EP0072351****AMINOGLYCOSIDE DERIVATIVES, PROCESSES FOR THEIR PRODUCTION, PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND SUCH DERIVATIVES FOR USE AS PHAR****EP0056408****GUANYLATED AMINOGLYCOSIDES, A PROCESS FOR THEIR PRODUCTION AND THEIR USE AS PHARMACEUTICALS.****WO 02/096455****USE OF POLYCLONAL IMMUNOGLOBULINS****WO0170272****POLYSACCHARIDE-POLYPEPTIDE CONJUGATE****WO0170264****METHOD FOR PRODUCING VACCINES CONTAINING A HEAT-TREATED MIXTURE CONSISTING OF AT LEAST ONE ANTIGEN AND OF AT LEAST ONE ADJUVANT****WO0135989****NOVEL USE OF ANTIBODIES AS VACCINES****List of publication****Hans Loibner, Ph.D.****September 2003**

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USE OF ANTIBODIES FOR ANTICANCER VACCINATION

WO9324647

ANTI-IDIOTYPIC MONOCLONAL ANTIBODIES AGAINST THE LEWIS Y-SPECIFIC  
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